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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/733,855	<b>Applicant(s)</b> CARR ET AL.	
	<b>Examiner</b> Frank W. Lu	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 and 30 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's response to the office action filed on August 22, 2007 has been entered. The claims pending in this application are claims 1-18 wherein claims 1-3 and 6-10 have been withdrawn due to restriction requirements mailed on June 2, 2006. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on August 22, 2007. Therefore, claims 4, 5, and 11-18 will be examined.

### ***Claim Objections***

2. Claim 4 or 5 is objected to because of the following informality: "newly synthesized nucleic acid" should be "synthesized nucleic acid" because, from the claim, there is no difference between "newly synthesized nucleic acid" in steps c) and d) and "synthesized nucleic acid" in step (a).

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. New Matter

Claims 5, 11-15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A limitation “based on results from the step of monitoring, detecting errors in the sequence of the newly synthesized nucleic acid” is added to the newly amended independent claim 5 and exists in newly added claim 14. Although the paragraphs [0029], [0030], [0134], and [0135] and Figures 14A and 14B of the specification as suggested by applicant describes that monitoring the deprotection of the 5' group is necessary to eliminate deletion errors, the specification fails to define or provide any disclosure to support such claim limitation because the specification does not describe that, based on results from the step of monitoring, detecting any kind of errors such as insertion errors in the sequence of the newly synthesized nucleic acid. A limitation “detecting change in electrophoretic force exerted by the newly synthesized growing nucleic acid as it grows” is added to the newly amended claim 12 and exists in newly added claim 15. However, the paragraphs [0022], [0118]-[0120], and [0135], Figures 9A and 14B, and original filed claim 6 of the specification as suggested by applicant fails to define or provide any disclosure to support such claim limitation.

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE

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WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 11-13, 15, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 5 is rejected as vague and indefinite. Since the claim does not indicate the correlation between monitoring the deprotection of the 5' protecting group and detecting errors in the sequence of the newly synthesized nucleic acid, it is unclear why errors in the sequence of the newly synthesized nucleic acid can be detected based on results from the step of monitoring. Please clarify.

8. Claim 12 is rejected as vague and indefinite because it is unclear why change in electrophoretic force can be exerted by the newly synthesized growing nucleic acid as it grows. Please clarify.

9. Claim 13 or 16 is rejected as vague and indefinite because it is unclear that a plurality of what reactions are carried out in parallel using plurality of light sources and detectors. Please clarify.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 4 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Gascoyne *et al.*, (US 2003/0171325, filed on September 11, 2003).

Regarding claim 4, Gascoyne *et al.*, teach providing a solid support for synthesis of nucleic acid, synthesizing nucleic acid attached to the solid support (ie., the beads) (see pages 3 and 4, and [0033] to [0038]), passing the solid support and newly synthesized nucleic acid through a channel opening (ie., transporting the beads attached synthesized oligos into top right of the center channel wherein the center channel is a channel with an opening, see page 4, [0039] and [0040] and page 13, [0152] and Figure 1), detecting errors in the sequence of the newly synthesized nucleic acid, and correcting errors in the sequence of the newly synthesized nucleic acid (see pages 4-7, and [0048] to [0079]).

Regarding claim 17, Gascoyne *et al.*, teach that the errors in the sequence of the newly synthesized nucleic acid are selected from the group consisting of insertion errors, deletion errors, and wrong base incorporation errors (see page 1, [0013] and [0014]).

Therefore, Gascoyne *et al.*, teach all limitations recited in claims 4 and 17.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gascoyne *et al.*, as applied to claims 4 and 17 above, and further in view of White *et al.*, (US Patent No. 7,062,385 B2, filed on November 25, 2002).

The teachings of Gascoyne *et al.*, have been summarized previously, *supra*.

Gascoyne *et al.*, do not disclose that a plurality of reactions are carried out in parallel using plurality of light sources and detectors as recited in claim 16. However, Gascoyne *et al.*, teach that the reaction (ie., detecting and correcting errors) is carried out using a light source (ie., fluorescent dye) and a detector (ie., fluorescent detector) (see pages 4 and 5, [0048] to [0058]).

White *et al.*, teach that a system comprising plurality of light sources and detectors as recited in claim 13 (see column 6, lines 1-31).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 16 wherein a plurality of reactions are carried out in parallel using plurality of light sources and detectors in

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view of the prior art of Gascoyne *et al.*, and White *et al.*. One having ordinary skill in the art would have been motivated to do so because the system comprising plurality of light sources and detectors taught by White *et al.*, has high sensitivity, discrimination, and detection capability for a variety of target analytes (see column 5, lines 1-20). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to perform the method recited in claim 13 using the system comprising plurality of light sources and detectors taught by White *et al.*.

### *Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. No claim is allowed.



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16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

November 8, 2007

  
FRANK LU  
PRIMARY EXAMINER